

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

MDL No. 01-1396 (JRT/FLN)

IN RE: ST. JUDE MEDICAL, INC.
SILZONE HEART VALVES
PRODUCTS LIABILITY LITIGATION

**MEMORANDUM OPINION
AND ORDER ON PLAINTIFFS'
RENEWED MOTION FOR CLASS
CERTIFICATION**

Steven E. Angstreich and Carolyn Lindheim, **LEVY, ANGSTREICH, FINNEY, BALDANTE, RUBENSTEIN & COREN, P.C.**, 10 Melrose Avenue, Suite 100, Cherry Hill, NJ 08003; James T. Capretz, **CAPRETZ & ASSOC.**, 5000 Birch Street, Suite 2500, West Tower, Newport Beach, CA 92660; David M. Cialkowski, J. Gordon Rudd, Jr., and Charles S. Zimmerman, **ZIMMERMAN REED, P.L.L.P.**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402; Joe D. Jacobson, **GREEN JACOBSON & BUTSCH, P.C.**, 7733 Forsyth Boulevard, Suite 700, St. Louis, MO 63105; and Daniel W. Sigelman, **COHEN, MILSTEIN, HAUSFIELD & TOLL, P.L.L.C.**, 1100 New York Avenue N.W., West Tower, Suite 500, Washington, D.C. 20005, for plaintiffs.

David E. Stanley, **REED SMITH**, 355 South Grand Avenue, Suite 2900, Los Angeles, CA 90071; Steven M. Kohn, **REED SMITH**, 1999 Harrison Street, Suite 2400, Oakland, CA 94612; and Michael T. Nilan and Tracy J. Van Steenburgh, **HALLELAND, LEWIS, NILAN, SIPKINS & JOHNSON**, 220 South Sixth Street, Suite 600, Minneapolis, MN 55402, for defendant.

Defendant St. Jude Medical produced the Silzone prosthetic heart valve. A test conducted by defendant showed a higher risk of paravalvular leaks at the site where the valves were implanted, and defendant voluntarily recalled all Silzone valves that had not yet been implanted. Numerous lawsuits were filed across the nation, and the cases filed in federal district courts were ultimately consolidated for joint pretrial proceedings in the

District of Minnesota. On motions by the plaintiffs, this Court issued three orders that collectively had the result of certifying two classes. Defendant appealed the two class certifications, and the Eighth Circuit reversed and remanded for further proceedings. This matter is now before the Court on plaintiffs' renewed motion for certification of a nationwide consumer protection class. For the reasons discussed below, the Court grants plaintiffs' motion.

BACKGROUND

Plaintiffs alleged common law strict liability, breach of implied and express warranties, negligence, and medical monitoring, and claims under various consumer protection statutes in Minnesota. Plaintiffs originally sought certification of two classes: a medical monitoring class and an injury class. The medical monitoring class sought primarily injunctive relief and was to include every patient in the United States who still has a Silzone valve implanted. The injury class sought damages and was to consist of all people in the United States who received a Silzone valve and who sustained physical injuries due to the valve.

On April 18, 2001, the Judicial Panel on Multidistrict Litigation transferred the cases comprising this multidistrict litigation to this Court for consolidated pretrial proceedings under 28 U.S.C. § 1407. The Court has issued many orders, three of which are relevant here.

On March 27, 2003, the Court issued an Order on plaintiffs' request for class certification. The Court certified claims under Minnesota's consumer protection and deceptive trade practices acts pursuant to Federal Rule of Civil Procedure 23(b)(3). The

Court conditionally certified the common law claims for both classes pursuant to Rule 23(b)(3) and 23(c)(4), and also conditionally certified the medical monitoring class pursuant to Rule 23(b)(2). The Court requested briefing on what minimum number and type of subclasses would be appropriate for plaintiffs' negligence, strict liability, breach of warranty, and medical monitoring claims.

On January 5, 2004, the Court issued an Order addressing the subclass issue. Of the conditionally certified claims, the Court determined that only the medical monitoring claims would remain. The Court defined the medical monitoring class as those plaintiffs whose valves were implanted in states that recognize a stand-alone cause of action for medical monitoring, absent proof of injury. The Court determined that the variation in state law would make a class action unmanageable for the personal injury class based on common law claims. The Court continued to certify the claims under Minnesota's consumer protection statutes.

In an Order dated July 15, 2004, the Court concluded that three additional states could be included in the medical monitoring class as a separate subclass. Following this third order, two certified classes remained: one based on Minnesota consumer protection statutes and another involving the medical monitoring claims.

On October 12, 2005, the Eighth Circuit issued an order reversing the class certifications and remanding for further proceedings. *In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, 425 F.3d 1116 (8th Cir. 2005). The Eighth Circuit reversed the medical monitoring class, concluding that diverse factual and legal issues preclude class certification. Specifically, the Eighth Circuit found that each

plaintiff's need for medical monitoring is highly individualized, and that states recognizing medical monitoring as a cause of action have different elements triggering culpability.

As for the consumer protection class, the Eighth Circuit reversed and remanded for more analysis. The Eighth Circuit stated that it could not determine whether this Court's choice of Minnesota law was constitutionally permissible because "the court did not analyze the contacts between Minnesota and each plaintiff class member's claims." The court remanded for the "proper choice-of-law analysis," citing *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 822-23 (1985).

On January 10, 2006, plaintiffs filed a renewed motion for an Order certifying a nationwide consumer protection class under Minnesota's consumer protection statutes and the Private Attorney General Act. Specifically, plaintiffs request that the Court certify a class of "all Silzone prosthetic heart valve patients in the United States who have not undergone an explant of their Silzone valve or developed a manifest and diagnosed injury from their Silzone implant of degree or severity that would permit individual personal injury lawsuits to be commenced in their State of residence."

ANALYSIS

The Eighth Circuit reversed and remanded the consumer protection subclass for further analysis on two discrete issues. First, the Court must address whether Minnesota has sufficient contacts with each plaintiff's claims so that application of Minnesota law satisfies the constitutional requirements of the Due Process Clause and Full Faith and Credit Clause. Second, if Minnesota has sufficient contacts to satisfy the constitutional

requirements, the Court must apply Minnesota's conflicts of law rules to determine whether application of Minnesota law is preferable over the law of other states with sufficient contacts.

The Court has already determined that the consumer protection class satisfies the threshold requirements of Rule 23(a), and that it can be maintained pursuant Rule 23(b)(3). *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*, 2003 WL 1589527 (D. Minn. March 27, 2003). Because the Court has determined that this detailed analysis remains applicable, it need not be repeated here.¹

I. Significant Contact Analysis Under The Due Process Clause And Full Faith And Credit Clause

The Due Process Clause and the Full Faith and Credit Clause provide “modest restrictions” on the application of forum law to class actions.² *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 818 (1985). The forum must have “‘significant contact or significant aggregation of contacts’ to the claims asserted by each member of the plaintiff

¹ Defendant emphasizes that the Eighth Circuit reversed the medical monitoring class based on a determination that medical monitoring is highly individualized, and uses this fact to argue that certification is not possible for the class based on consumer protection statutes because plaintiffs seek relief in the form of medical monitoring. If this argument had merit, the Eighth Circuit would have concluded that certification of the consumer protection class was not possible, just as it did for the medical monitoring class. Plaintiffs' claims are based on Minnesota's consumer protection statutes, and the Court does not find that the fact that plaintiffs seek medical monitoring relief precludes class certification. Plaintiffs also seek relief in the form of an epidemiological study, which is undoubtedly uniform across all class members and ideally suited for a class action.

² Analysis under the Due Process Clause and the Full Faith and Credit Clause collapse into a single inquiry under the Due Process Clause. *See Allstate Ins. Co. v. Hague*, 449 U.S. at 308, n.10.

class, contacts ‘creating state interests,’ in order to ensure that the choice of [forum] law is not arbitrary or unfair.” *Id.* at 821-22, quoting *Allstate Ins. Co. v. Hague*, 449 U.S. 302 (1981). In many situations, there will be several constitutionally permissible choices of law. *Shutts*, 472 U.S. at 823.

The first step in this analysis is to determine whether the law of the forum “conflicts in any material way with any other law which could apply.” *Shutts*, 472 U.S. at 816 (explaining that application of forum law causes no injury if it is not in conflict with that of any other jurisdiction connected to the lawsuit). Here, the forum state is Minnesota, and all fifty states are connected to this lawsuit because Silzone devices were implanted and individual class members reside in every state in the nation. As discussed below, the Court concludes that 18 states have substantive conflicts with the consumer protection laws of Minnesota.

Given these conflicts of law, the Court next considers whether applying the law of the forum would be fair. When making this assessment, the court must consider whether the forum has significant contacts to the litigation that support the forum state’s interest in applying its law. *Id.* at 819, citing *Allstate Ins. Co. v. Hague*, 449 U.S. at 313-329. Another important consideration is the “expectation of the parties.” *Shutts*, 472 U.S. at 822.

In its order reversing and remanding this case, the Eighth Circuit explained that application of the law of Minnesota “ultimately may be proper” but that this Court needed to conduct further analysis. *In re St. Jude Medical*, 425 F.3d 1116, 1119-20 (8th Cir. 2005). Accordingly, the Court has analyzed the contacts between Minnesota and

each class member's claims, and determines that application of Minnesota law is fair. Minnesota has significant contacts with each class member by virtue of the domicile and claims-related activities of defendant. *See Northwest Airlines v. Astraea Aviation Servs.*, 111 F.3d 1386, 1394 (8th Cir. 1997) (holding that defendant's headquarters and conduct in Texas comprise "significant contacts" under the Due Process Clause). The Court need not specifically discuss Minnesota's contacts to each of over 11,000 class members' claims because each class member's claims have in common the following contacts with Minnesota.

First, defendant is incorporated, headquartered, and has its principal place of business in Minnesota. These physical and corporate domiciliary contacts support Minnesota's interest in applying its law. Minnesota has an interest in regulating its domestic corporations, and ensuring that out-of-state persons doing business with Minnesota firms may rely on their compliance with Minnesota statutes. *See CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 93 (1987) ("[The forum state] has a substantial interest in preventing the corporate forum from becoming a shield for unfair business dealing.").

Second, virtually all of the corporate acts implicated by each claim occurred in Minnesota. *Cf. Shutts*, 474 U.S. at 815 (reversing application of Kansas law to the entire class where over 99% of the gas leases at issue had no apparent connection to Kansas). Plaintiffs' claims are based on alleged false representations and material omissions regarding the safety and efficacy of the Silzone valves through defendant's global advertising, marketing, and product labeling. Importantly, all marketing and distribution

efforts were based in Minnesota, and all labels and instructions were drafted in Minnesota.

Third, the Silzone heart valves were substantially created and manufactured in Minnesota. Specifically, defendant explains that the valves were “designed, researched, developed, engineered, manufactured, tested, [and] quality controlled in Minnesota.” In addition, the related FDA and other regulatory affairs were managed and controlled from defendant’s headquarters in Minnesota.

Finally, defendant invited heart valve purchasers and recipients to solicit more product information from Minnesota by including a Minneapolis, Minnesota telephone number in journal advertisements worldwide.

In addition, the invitation to place phone calls to Minnesota, along with the corporate and physical domiciliary contacts with Minnesota, affects the expectations of the parties on which law would apply to potential claims. Obviously, the application of Minnesota law to a Minnesota corporation could not be unexpected for defendant. To the extent that class members were even thinking about these issues when they received their heart valves, the Court finds that individual class members would have expected a plainly Minnesota-based corporation to be subject to the requirements of Minnesota statutes.

Given defendant’s significant contacts with Minnesota, no one would doubt that an individual class member could sue defendant in Minnesota and apply Minnesota law. Similarly, the Court concludes that it is constitutionally permissible to apply Minnesota law in the class action context.

II. Application Of Minnesota's Conflict Of Laws Rules

Although the Court concludes that application of Minnesota law is constitutionally permissible, a conflict of laws analysis is necessary to determine if application of Minnesota law is preferable to the law of each plaintiff's home state, or state where the valve was implanted. The Court must therefore apply Minnesota's conflict of laws rules. *See Nesladek v. Ford Motor Co.*, 46 F.3d 734 (8th Cir. 1995) (holding that federal courts sitting in diversity apply the forum state's conflict of laws rules). This analysis requires consideration of the five "choice-influencing" factors for each state where there is a substantive conflict of law. *See Nodak Mut. Ins. Co. v. American Family Mut. Ins. Co.*, 604 N.W.2d 91, 94 (Minn. 2000).

A. Substantive Conflicts of Law Exist

Before proceeding with the choice-of-law analysis, the Court needs to determine whether there are any conflicts of law, and whether those conflicts are substantive, rather than procedural. If there is no conflict of substantive law, then the law of the forum applies without further analysis. *Richie v. Paramount Pictures Corp.*, 544 N.W.2d 21, 29 (Minn. 1996).

Plaintiffs have provided the Court with a detailed analysis of consumer protection statutes across the United States. Plaintiffs used an "outcome determinative" standard to see if a cause of action based on the facts they have alleged would be precluded under the laws of other states. *See Schumacher v. Schumacher*, 676 N.W.2d 685, 689 (Minn. Ct. App. 2004) ("A conflict of law exists if choosing the law of one state over the law of another state would be 'outcome determinative.'"). Based on this sound analysis, the

Court concludes that 32 jurisdictions have no outcome determinative conflicts with Minnesota law.³ Application of Minnesota law to plaintiffs with significant contacts in these jurisdictions is therefore warranted without further analysis. The remaining 18 states have substantive conflicts of law,⁴ and thus require application of the five-factor test.

B. Consideration of the Choice-Influencing Factors

Where a true conflict of substantive law exists, Minnesota courts resolve the conflict by considering the following five “choice-influencing” factors: 1) predictability of results; 2) maintenance of interstate and international order; 3) simplification of the judicial task; 4) advancement of the forum’s government interest; and 5) application of the better rule of law. *Nodak*, 604 N.W.2d at 94.

³ The Court finds that the following jurisdictions have no outcome determinative conflicts with Minnesota law: Alaska, California, Connecticut, Delaware, District of Columbia, Florida, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Rhode Island, South Carolina, Tennessee, Vermont, Washington, and West Virginia. The Court disagrees with plaintiffs’ assessment that Utah does not require scienter. *See* Utah Code § 13-11-4(2) (“[A] supplier commits a deceptive act or practice if the supplier knowingly or intentionally [engages in the conduct enumerated in this section].”).

⁴ These substantive conflicts are based on the type of scienter required, whether individual reliance is required, whether the state recognizes a private cause of action, and whether material omissions are prohibited. The Court finds that the following jurisdictions have outcome determinative conflicts with Minnesota law: Alabama, Arizona, Arkansas, Colorado, Georgia, Indiana, Iowa, Maryland, Nevada, New Mexico, Oklahoma, Pennsylvania, South Dakota, Texas, Utah, Virginia, Wisconsin, and Wyoming.

1. Predictability of Results

This factor addresses “whether the choice of law was predictable before the time of the transaction or event giving rise to the cause of action.” *Danielson v. Nat’l Supply Co.*, 670 N.W.2d 1, 7 (Minn. Ct. App. 2003). This factor applies primarily to contractual and other “consensual transactions where the parties desire advance notice of which state law will govern in future disputes.” *Nodak*, 604 N.W.2d at 94. For claims based on tort, on the other hand, this factor has little relevance because the occurrence of torts is unpredictable. *See Nesladek v. Ford Motor Co.*, 46 F.3d 734, 738 (8th Cir. 1995).

A cause of action under consumer protection statutes is not based entirely in either tort or contract law. To the extent that this factor is relevant here, it weighs toward the application of Minnesota law because there is no indication that plaintiffs or defendant reasonably expected that another state’s law would apply. Over 80 percent of defendant’s medical contracts with hospital or clinic purchasers contain a provision in which Minnesota law was selected as the governing law. Moreover, defendant could easily predict that it would be subject to the laws of Minnesota, and it is less burdensome to expect defendant to understand and follow the laws of its home state than the consumer protection laws of all fifty states.

2. Maintenance of Interstate and International Order

This factor addresses “whether the application of Minnesota law would show manifest disrespect for [another state’s] sovereignty or impede the interstate movement of people and goods.” *Jepson v. General Cas. Co. of Wisconsin*, 513 N.W.2d 467, 471 (Minn. 1994). “The factor is generally not implicated if the state whose law is to be

applied has ‘sufficient contacts with and interest in the facts and issues being litigated.’” *Hughes v. Wal-Mart Stores, Inc.*, 250 F.3d 618, 620 (8th Cir. 2001) (quoting *Myers v. Gov’t Employees Ins. Co.*, 225 N.W.2d 238, 242 (Minn. 1974)). A comparison of contacts is made only when a forum state “has little or no contact with a case and nearly all of the significant contacts are with a sister state.” *Hughes*, 250 F.3d at 620-621. As discussed above, the Court concludes that Minnesota has significant contacts with each plaintiff’s claims by virtue of the domicile and claims-related activities of defendant.⁵ Accordingly, the Court finds that this factor does not preclude the application of Minnesota law.

3. Simplification of the Judicial Task

This factor concerns this Court’s ability to discern and apply the law of a state other than Minnesota. This factor favors application of Minnesota law because it would be simpler to apply the law of one state than the law of multiple states.

4. Governmental Interest

Under this factor, the Court must weigh the policy interests of Minnesota with those of other states with connections to this litigation. *See Nesladek v. Ford Motor Co.*, 46 F.3d 734, 739 (8th Cir. 1995). Minnesota has a compelling interest in redressing wrongs committed within its borders. Specifically, there is a moral interest in providing

⁵ In addition, the reality of forum shopping may be taken into account under this factor. *Stenzel v. State Farm Mut. Auto. Ins. Co.*, 379 N.W.2d 674, 676 (Minn. Ct. App. 1986). This Court obtained jurisdiction pursuant to the multi-district litigation jurisdictional grant and on defendant’s motion to transfer, so plaintiffs cannot be accused of forum shopping.

redress for those who are injured. *See Boatwright v. Budak*, 625 N.W.2d 483, 489 (Minn. Ct. App. 2001). There is also an economic interest because when out-of-state persons are harmed by illegal actions of Minnesota businesses, the reputations of other Minnesota businesses are also tarnished. *See State ex rel. Corbin v. Pickrell*, 667 P.2d 1304, 1312 (Ariz. 1983).

Although Minnesota clearly has a strong interest in policing the conduct of its own corporations, the Court recognizes that other states may have interests in applying their relevant laws to the marketing, sale, and implantation of medical devices within their borders. In all jurisdictions that have substantive conflicts with Minnesota consumer protection laws, those jurisdictions have more stringent liability standards.⁶ These jurisdictions may have a strong interest in applying these standards to protect local defendants, but the Court cannot find that these jurisdictions would have such a strong interest in applying their own laws that they would seek to prevent an action that would benefit their own citizens. *See Downing v. Abercrombie & Fitch*, 265 F.3d 994, 1007 (9th Cir. 2001) (dismissing as “pure fancy” the suggestion that Hawaii would wish to restrict its residents from recovery that others could obtain under California law). Even though the liability standards differ from Minnesota laws, the policy interests of these jurisdictions are still furthered through the application of Minnesota law to their citizens because all consumer fraud laws in the nation are designed to protect consumers to some

⁶ Plaintiffs have provided the Court a side-by-side comparison of consumer protection laws for all 50 states, and the Court adopts this thorough analysis.

degree. *See Int'l Union of Operating Eng's Local #68 Welfare Fund v. Merck & Co.*, 894 A.2d 1136 (N.J. App. Div. 2006).

Defendant emphasizes that in tort claims this factor generally points to application of law from where the injury occurred. However, the Court believes that a different conclusion must be reached for claims based on consumer protection statutes. Consumer protection statutes focus on the behavior of the defendant, and therefore it is appropriate to apply law from where the defendant has the most contacts. *See* Restatement (Second) Conflict of Laws § 145 cmt. e (explaining that in cases of misrepresentation or fraud the place of injury has little importance). In short, the Court finds no basis for a Minnesota corporation manufacturing a product in Minnesota to escape liability from consumer protections laws in Minnesota merely because plaintiffs have contacts with other states.

5. Better Rule of Law

Minnesota courts have stated that this factor carries essentially no weight, so the Court finds it unnecessary to address it. *See Nodak*, 604 N.W.2d at 96.

III. Conclusion

The Court finds that Minnesota has significant contacts with each plaintiff's claims, such that application of Minnesota law to these claims is constitutionally permissible. After a detailed conflict of laws analysis, the Court concludes that Minnesota law should be applied to plaintiffs' claims over the laws of other jurisdictions with connections to this litigation. It is difficult for the Court to imagine how over 11,000 individual consumer fraud cases could be handled effectively against the

defendant. It is equally difficult to try to apply the consumer protection statutes of the various states in a manner that can efficiently resolve this litigation. Certification of a consumer protection class clearly provides the most effective manner in which to resolve these misrepresentation and deceptive trade practices claims and it is clear to the Court that it is most fair to plaintiffs and to defendants to apply Minnesota law to these claims within the boundaries and restrictions of a class action. Based on these findings, and the Court's finding that class certification remains appropriate under Rule 23, the Court grants plaintiffs' renewed motion for class certification.

ORDER

Based upon the foregoing, the submissions of the parties, the arguments of counsel and the entire file and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiffs' Renewed Motion To Certify Consumer Protection Subclass [Docket No. 408] is **GRANTED**.

DATED: October 13, 2006
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge